

Notice of Allowability

Application No.

10/656,863

Examiner

Jason M. Nolan, Ph.D.

Applicant(s)

KLEY ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 09/05/2003.
2. ☒ The allowed claim(s) is/are 1-7.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>8/16/2004</u> | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Claims 1-7 are currently pending in the application.

Priority

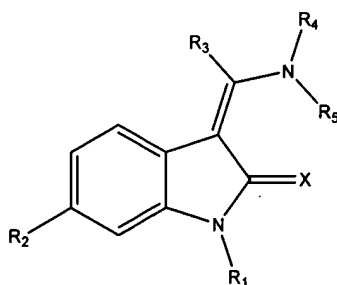
Acknowledgement is made of Applicant's claim for priority via US Provisional 60/414,938 filed on September 30, 2002 and 60/430,790 filed on December 04, 2002, which are translations of foreign patent applications DE 102 42 350.4, filed on September 12, 2002 and DE 102 52 969.8, filed on November 14, 2002 in Germany.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on August 16, 2004 is in compliance with the provisions of 37 CFR § 1.97 and was considered by the examiner.

Reasons for Allowance

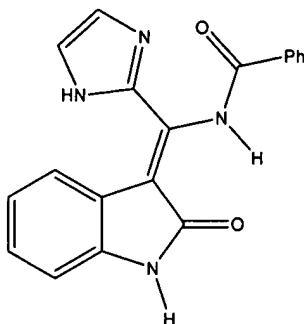
The following is an examiner's statement of reasons for allowance: The compounds and compositions according to Claim 1 are free of the prior art. The present invention is compounds and compositions of the general formula:



These compounds are free of the prior art due to the limitations of R₁, R₃ and R₄, wherein R₁ is a hydrogen atom or a prodrug group (functional group containing a carbonyl), R₃ is a heterocycle or phenyl-bicyclic moiety, and R₄ is cycloalkyl or phenyl.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Kandile et al. *Revue Roumaine de Chimie* **1991** 36 (1-3), 245.



Kandile et al. 1991

As stated above, the instant application limits the substitution of R^4 to a cycloalkyl or phenyl moiety, and in the compound presented by Kandile et al., the R^4 substituent is a carbonyl (phenyl amide). For this reason the compounds according to the formula of Claim 1 are patentably distinct from this art.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Roth et al. US Patents 6,762,180, issued 7/2004, and 6,858,641, issued 2/2005. These patents are similar in structure to the current application such that *heteroaryl* is listed in Claim 1 as a substituent for R^3 , however no motivation exists with respect to double patenting due to the further limitations set forth in later claims. In 6,762,180 Roth et al. specifies alkyl or phenyl substituents in Claim 3 and in 6,858,641 Roth et al. specifies phenyl or naphthyl substituents in Claim 3.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 1-7 are allowed.

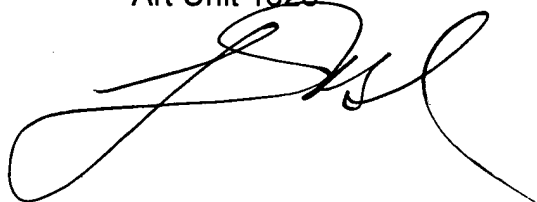
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jason M. Nolan, Ph.D. whose telephone number is (571) 272-4356. The Examiner can normally be reached on Monday - Friday (9:00 - 5:30PM).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jason M. Nolan, Ph.D.
Patent Examiner
Art Unit 1626



KAMAL A. SAEED
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for Kamal Saeed
Joseph McKane
Supervisory Patent Examiner
Art Unit 1626
Date: November 22, 2005